DEPARTMENT OF HEALTH AND HUMAN SERVICES

APR 5 1995

Hector Quemada, Ph.D.
Associate Director
Experimental Plant Genetics
Asgrow Seed Company/Upjohn
7000 Portage Road
Kalamazoo, MI 49001

Dear Dr. Quemada:

This is in regard to your genetically modified squash about which you initiated consultations with the agency in September 1992. The new squash variety has been modified for resistance to watermelon mosaic virus 2 and zucchini yellow mosaic virus by insertion of the coat protein genes from the two viruses.

As part of bringing your consultation with FDA regarding this product to closure, you submitted a summary of your safety and nutritional assessment of the new squash variety on September 6, 1994. On October 3, 1994, you also made a detailed oral presentation of the data that support your submission. It is our understanding that these communications were intended by Asgrow to inform FDA of the steps taken to ensure that this product complies with those legal and regulatory requirements that fall within FDA's jurisdiction. Further, it is our understanding that, based on the safety and nutritional assessment you have conducted, you have concluded, in essence, that the new squash variety is not materially different in composition, safety, or any other relevant parameter from squash varieties currently on the market and that it does not raise issues that would require premarket review or approval by FDA. All materials relevant to this consultation have been placed in a file that has been designated BNF 0006 and that will be maintained in the Office of Premarket Approval.

Based on the description of the data and information presented during the consultations, the new squash variety does not appear to be significantly altered within the meaning of 21 CFR 170.30(f)(2). We have no additional questions concerning this product at this time. However, as you are aware, it is Asgrow's continued responsibility to ensure that foods the firm markets are safe, wholesome and in compliance with all applicable legal and regulatory requirements.

Sincerely yours,

/S/

Alan M. Rulis, Ph.D.
Acting Director
Office of Premarket Approval
Center for Food Safety
and Applied Nutrition